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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

006242

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 6 1985

MEMORANDUM

SUBJECT: EPA File Symbol 3125-GAA
Gemini 8 Emulsifiable Concentrate Herbicide

FROM: Mary L. Waller
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: Mobay Chemical Corporation
Agricultural Chemicals Division
P.O. Box 4913
Kansas City, MO 64120

ACTIVE INGREDIENTS:

2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxyl-1-methylethyl)acetamide	73.6%
4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one	17.2%
INERT INGREDIENTS:	9.2%

BACKGROUND:

The applicant has submitted a dermal sensitization, acute oral, acute dermal, primary eye irritation, primary skin irritation, and acute inhalation studies. The studies were conducted by Mobay Chemical Corporation. The data Accession Numbers are 258449 for the dermal sensitization study and 258450 for the other studies. The method of support was not indicated.

RECOMMENDATION:

FHB/TSS finds all data acceptable to support registration. Consideration will be given to upgrading the dermal sensitization

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study classification (supplementary) if the registrant provides the individual irritation scores for each animal after each induction treatment. The signal word is CAUTION.

LABELING:

The following label revisions must be made:

1. Expand the first sentence in the Precautionary Statements as follows: May be harmful if swallowed, inhaled or absorbed through skin.

2. Delete the following sentence under the Precautionary Statements and place it under the Directions for Use: Do not contaminate feed or food.

3. Move the information under the subheading "Ground Water Advisory" and the heading "RE-ENTRY STATEMENTS" and place them under the Directions for Use.

REVIEW:

(1) Dermal Sensitization Study: Mobay Chemical Corporation; Report No. 625; May 3, 1985.

PROCEDURE:

Fifteen male guinea pigs received three induction doses each of 0.5 ml of 90 percent test material in deionized water applied to a shaven test site on the left flank. Test sites were kept under occlusive wrap for 6 hours. Two weeks later, an identical challenge dose was administered to the 15 animals at the original (left flank) test site and a new site (right flank). Another group of five males received the same challenge dose applied to a shaven test site. Animals were weighed on days 0 and 31 after the study. Skin irritation was observed and scored for erythema at 24 and 48 hours after each induction treatment for each animal. Skin irritation was observed to score erythema at 48 and 72 hours after challenge dose.

RESULTS:

Induction scores were not provided. At 48 hours, 15/15 animals receiving both induction and challenge doses exhibited slight, barely perceptible erythema on the left flank and no irritation on the right flank (new site). At 72 hours, 8/15 animals exhibited slight, barely perceptible erythema on the left flank and no irritation on the right flank. At 24 hours, 1/5 animals receiving only the challenge dose exhibited slight, barely perceptible erythema and at 48 hours, 3/5 animals exhibited slight, barely perceptible erythema.

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STUDY CLASSIFICATION: Supplementary - See comments under Recommendation.

(2) Acute Oral Toxicity Study: Mobay Chemical Corporation; Report No. 576; February 1, 1985.

PROCEDURE:

Groups of five male Sprague-Dawley rats were administered one dose of test material by oral intubation as follows: 1450, 1653, 1885, 2450, 3185 or 4140 mg/kg. Groups of five female Sprague-Dawley rats were administered one dose of test material by oral intubation as follows: 752, 855, 1115, 1450, 1885, 2450 and 3185 mg/kg. Animals were weighed on day of dosing and at 7 and 14 days. Observations were conducted daily for 14 days. Gross necropsy was performed on all animals.

RESULTS:

The following female mortalities were observed: at 1650 mg/kg, 3/5 died; at 1885 mg/kg, 4/5 died; at 2450 mg/kg, 2/5 died; and at 3185 and 4140 mg/kg, all animals died. The following male mortalities were observed: at 752 and 858 mg/kg, 2/5 died; at 1115 mg/kg, 5/5 died; at 1450 mg/kg, 4/5 died; and at 1885, 2450 and 3185, all animals died. The LD_{50} for males was reported to be 1876 mg/kg with 95 percent confidence limits of 1529 to 2292 mg/kg. The LD_{50} for females was reported to be 849 mg/kg with 95 percent confidence limits of 573 to 1235 mg/kg.

Toxic symptoms included salivation, decreased or increased activity, lacrimation, ataxia, hyperreactivity, diarrhea, unthriftiness, ptosis, piloerection, and red nasal discharge.

Gross necropsy revealed external lesions, red nasal discharge, red urinary discharge, fluid-filled gastrointestinal tract, reddened cervical lymph nodes, dark pink lungs, and reddened depressed area of the gastric mucosa.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(3) Acute Dermal Toxicity Study: Mobay Chemical Corporation; Report No. 548; November 8, 1984.

PROCEDURE:

Five male and five female New Zealand White rabbits were shaved and 24 hours later, 2000 mg/kg of test material was

applied to the shaven test sites under occlusive wrap. After 24 hours of exposure, wrap was removed and test sites wiped clean. Animals were weighed on the day of treatment and on days 7 and 14. Observations for mortality and toxic symptoms were conducted daily for 14 days. All animals were subjected to gross necropsy.

RESULTS:

No deaths occurred. The LD_{50} was reported to be > 2000 mg/kg. Very slight skin irritation was present after exposure and cleared by 24 hours. No abnormalities were noted at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(4) Primary Eye Irritation Study; Mobay Chemical Corporation; Report No. 565; January 2, 1985.

PROCEDURE:

Six New Zealand White rabbits were treated with 0.1 ml of test material placed in the left eye. The other eye served as a control. The treated and control eyes were examined at 1, 24, 48 and 72 hours and at 7 days.

RESULTS:

Eye irritation was scored as follows: at 24 hours, conjunctivae redness (2/6 = 2, 4/6 = 1), chemosis (1/6 = 2, 5/6 = 1) and discharge (1/6 = 2, 2/6 = 1); and by 7 days, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(5) Primary Skin Irritation Study: Mobay Chemical Corporation; Report No. 559; December 4, 1984.

PROCEDURE

Six New Zealand White rabbits were shaved and 24 hours later, 0.5 ml of test material was applied to the shaven test site and kept under occlusive wrap for 4 hours. After removal of wrap, the test sites were wiped clean. Observations to note skin irritation were made at 1, 24, 48 and 72 hours after exposure.

RESULTS:

Skin irritation was scored as follows: At 24 hours, 4/6 animals exhibited well-defined erythema, 2/6 exhibited very slight erythema, and 5/6 exhibited very slight edema, and at 72 hours, 6/6 exhibited very slight erythema, and 4/6 exhibited very slight edema.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(6) Acute Inhalation Toxicity Study: Mobay Chemical Corporation; Report No. 591; February 13, 1985.

PROCEDURE:

Groups of 10 male and 10 female Sprague-Dawley rats were exposed (head only) in a 60 liter chamber for 4 hours to one of the following analytical concentrations of test material aerosol: 1240, 1276, 1797, 2209, 2241 and 2884 mg/L. Two control groups of 10 males each and two control groups of 10 females each were exposed in the chamber under similar conditions to air for 4 hours. Observations for mortality and toxic symptoms were made during exposure and twice daily thereafter for 14 days except on weekends and holidays. Animal weights were recorded prior to exposure and on days 3, 7 and 14. Gross necropsy was performed on all animals.

RESULTS:

At 1240 mg/L, 2/10 females died. At 1276 mg/L, 2/10 males and 3/10 females died. At 1797 mg/L, 2/10 males and 3/10 females died. At 2209 mg/L, 3/10 males and 3/10 females died. At 2241 mg/L, 2/10 males and 3/10 females died. At 2884 mg/L, 9/10 males and 9/10 females died. The LC_{50} for males was reported to be 2332 mg/L with 95 percent confidence limits of 2036 to 2760 mg/L. The LC_{50} for females was reported to be 2077 mg/L.

Toxic symptoms included salivation, lacrimation, nasal and ocular irritation, decreased activity, urine stains, rales, labored breathing, tremors, and alopecia.

Gross necropsy revealed tan nasal discharge, fluid-filled intestines, reddened lungs and cervical lymph nodes, reddened turbinates, matted glossy haircoat, bilateral lacrimation and epistaxis.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category IV - CAUTION.